

Innovations in diagnostic methods for sexually transmitted infections

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In our first editorial as Editors in 2003, we anticipated some of the challenges that lay ahead in the field of sexually transmitted infections (STIs), and outlined a role for *STI* in providing both an evidence base and up-to-date reviews of key issues.¹ One key area was diagnostics:

"There are exciting developments in diagnostic techniques that increase sensitivity and specificity, identify subtypes, and may provide rapid answers in near patient tests. The impact of these advances is yet to be fully felt."¹

The impact is now starting to be felt, and we are addressing this in a number of ways in the journal. In this issue we include a debate on the motion that near-patient testing will improve the control of STIs. This topic was initially discussed at the Health Protection Agency conference in 2005, with contributions from Paul Ward and Gillian Dean.^{2,3} Ward outlines the potential contribution of point-of-care tests in reducing delays in accessing sexual health services through moving more testing outside of traditional clinics; empowering patients by allowing them a greater say in where, when and how they are tested; and health improvement through earlier diagnosis leading to fewer sequelae and less transmission. He also suggests a role for point-of-care tests in reducing inequalities and increasing patient choice. Countering this optimism, Dean queries the validity of many point-of-care tests and highlights the difficulties of dealing with patients who have false-positive results and the public health problem of missing cases due to false-negatives. She also questions whether it is appropriate to alter standards of care simply because healthcare providers move outside of a clinical setting, suggesting that patients should expect the best possible care, including the best possible tests, whether their healthcare interaction occurs in the surgery or in a club. Dean also expresses concern about the impact of point-of-care tests on surveillance of STIs.

Many of these issues are explored further in an editorial review by Rosanna Peeling from the Sexually

Transmitted Diseases Diagnostics Initiative (SDI).⁴ She assesses both the potential gains and pitfalls associated with the proliferation of testing. The combination of patient-collected specimens with simple and rapid tests using nucleic acid amplification technology means that people no longer have to visit a clinic to be tested for STIs. In addition to outreach testing venues or pharmacies, it is now possible to purchase tests via the internet. Peeling contrasts this availability with the lack of regulatory control of testing, and argues that this issue must be urgently addressed. She points out that without regulation we face the possibility of widespread misdiagnosis and consequent mismanagement of patients who are simply trying to look after their own sexual and reproductive health. Peeling has also edited a supplement on new diagnostics and this will be available online before the end of 2006. It contains results from evaluations of several new tests and will provide much needed evidence for those looking to introduce tests into daily practice. The supplement will be distributed with the next issue of *STI*.

Articles within the forthcoming supplement include large laboratory evaluations, individual test comparisons and background information on the work of the SDI. For example, Herring *et al*⁵ evaluated the performance of nine rapid tests for syphilis in a number of laboratories, and found sensitivities ranging from 84.5% to 97.7%, and specificities from 84.8% to 98%. In contrast, one specific test for syphilis, Determine, was evaluated in an outreach setting in Peru using blood from finger-prick samples.⁶ Unfortunately, the sensitivity was far lower than reported from previous studies of the same test based on serum samples. Another disappointing result is reported for a gonococcal test, NGThermo Biostar.⁷ This was evaluated in women at an STI clinic in Brazil, and found to have a sensitivity of 60% and a specificity of 90%. So even in this relatively high-risk group of women, with a prevalence of 15%, the tests only had a positive predictive value of 55.6%. The potential impact of rapid tests on sexual and reproductive health world-wide is enormous, but these results show that

for many conditions there is some way to go before this potential can be fully realised. Keeping up to date with developments in the area can be difficult, and the SDI has a useful section of its website that provides annotated abstracts and commentaries on relevant publications (www.who.int/std_diagnostics/literature_reviews). A short article in the supplement outlines how this is done.⁸

With this issue we include new screening and testing guidelines from the British Association for Sexual Health and HIV (BASHH). These evidence-based guidelines update and replace earlier versions, and include recommendations on routine screening as well as diagnostic tests. In a linked editorial,⁹ Ross and colleagues highlight key changes. These include no longer screening for non-specific urethritis in asymptomatic men, and the use of nucleic acid amplification tests (NAATs) rather than culture for the diagnosis of herpes.^{10,11}

A final contribution to this body of work on diagnostics is a discussion of whether more widespread use of nucleic acid amplification tests (NAATs) for gonorrhoea is appropriate. Cathy Ison, Director of the Health Protection Agency's Sexually Transmitted Bacteria Reference Laboratory, concludes, "The time is right to consider GC NAATs, but we should proceed with caution until we have a strong evidence base".¹²

As Editors we look forward over the coming years to further contributions to *STI* in the area of diagnostics to ensure that when the evidence base is strong we can provide further definitive guidance for our readers.

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Testing for sexually transmitted infections

A paradigm shift in testing for sexually transmitted infections

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A new set of UK guidelines on screening and testing for sexually transmitted infection

The way in which sexually transmitted infection (STI) services are delivered in the UK is hardly recognisable to those practising 20 or even 10 years ago, and the pace of change shows no sign of slowing. The changes have been driven by the need to modernise services and improve efficiency, and have had three main components: (1) improvements in information/communication technology; (2) new systems or pathways of care in clinics; (3) advances in diagnostic testing. Thus, we see the increased use of mobile phones and email to communicate with our patients, the integration of computer systems in laboratories with clinic computers, the use of the internet for health education and contact tracing, and also look forward to the holy grail of an electronic patient record.^{1–2} We are also learning to use these information/communication technologies in a more productive way by changing the skill mix of clinic staff and reviewing patient care pathways to allow more patients to be seen alongside maintaining a high-quality service.³

In this changing environment, we must not forget that the accurate and timely diagnosis of STIs remains a core function of any genitourinary medicine or sexual health clinic. New technologies offer the tantalising prospects of more accurate diagnosis, faster turnaround times, and the collection of specimens by patients themselves, without the need for an examination. However, these developments should be viewed in the context of new commissioning and funding arrangements in the UK that will determine how quickly they can be implemented at a local level. Payment by results (PbR) currently

pays a fixed tariff for each sexual health screen performed.⁴ But PbR is based on historical costs which do not incorporate these new laboratory technologies, and so, if we are to implement new tests to improve patient care, we have to agree to new standards. The specific issues are as follows:

- What constitutes an STI screen—which infections should be tested for and how should this be modified in the presence of different symptoms, sex or sexual orientation?
- What tests should be used for each infection—which tests are optimal or acceptable, and which are not recommended?
- What specimen should be used for each test?

The *Sexually transmitted infection screening and testing guidelines*⁵ provide an evidence-based approach to each of these issues. Commissioned by the Clinical Effectiveness Group of the British Association for Sexual Health and HIV, they have been developed under the appraisal of guidelines research and evaluation methodological framework,⁶ with contributions from over 20 national and international experts. The recommendations they contain were developed specifically for genitourinary medicine and sexual health clinics, but may also provide guidance in other healthcare settings which wish to optimise the diagnosis of STIs.

The guidelines are divided into two sections:

1. Summary tables: These recommend which tests should be taken and

from what sites. Separate tables are available for heterosexual men, women, men who have sex with men, those presenting with genital discharge and those presenting with genital ulceration.

2. Testing guidelines for individual STIs: A separate chapter for each STI provides further detail on testing options and the evidence base for recommendations.

The guidelines have been designed to help clinicians decide which tests are most appropriate for their patients and are not intended to be prescriptive, although many of the recommendations are already standard practice. However, some others will need a modification in practice. These include:

- not screening for non-specific urethritis in asymptomatic men
- the use of nucleic acid amplification tests (NAAT) in preference to culture to detect herpes because of its improved sensitivity
- the inclusion of NAATs for gonorrhoea, although the guidelines continue to recommend the isolation of *Neisseria gonorrhoeae* to confirm gonococcal infection until the commercially available tests have been fully evaluated with different specimen types and in populations with both high and low prevalence.

For many years, standard teaching and practice in the UK, but not in all parts of the world, has been that a Gram-stained urethral smear was required as part of the routine examination of all male patients. This is still clearly indicated as part of the examination of symptomatic men in whom a diagnosis of gonorrhoea is a real possibility, and in these cases the smear may provide a rapid diagnosis. However, the evidence no longer supports routinely performing the urethral smear in men without symptoms. Those who advocate its continued use in this situation argue that a noticeable minority of men (17–36%^{7–9}) with chlamydial urethritis will receive an immediate diagnosis and hence treatment, following to the detection of urethritis by microscopy. In others diagnosis and treatment would be delayed, pending the result of a specific